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Ropinirole Tablets

DEFINITION

Ropinirole Tablets contain ropinirole hydrochloride equivalent to NLT 90.0% and NMT 110.0% of the labeled amount of ropinirole free base ($C_{16}H_{24}N_2O$).

IDENTIFICATION

• **A.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.

Add the following:

▲• **B.** The UV spectrum of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.▲ (USP 1-Dec-2019)

ASSAY

Change to read:

• PROCEDURE

Buffer: 3.85 g/L of [ammonium acetate](#). Adjust with [phosphoric acid](#) to a pH of 2.5.

Mobile phase: [Acetonitrile](#), [methanol](#), and *Buffer* (7:3:40)

System suitability solution: 0.1 mg/mL of [USP Ropinirole Hydrochloride RS](#) and 0.5 µg/mL of [USP Ropinirole Related Compound B RS](#) in *Buffer*

Standard solution: 0.1 mg/mL of [USP Ropinirole Hydrochloride RS](#) in *Buffer*

Sample solution: Nominally 0.1 mg/mL of ropinirole in *Buffer*▲ (USP 1-Dec-2019) prepared as follows. ▲Transfer NLT 5 Tablets into a suitable volumetric flask and▲ (USP 1-Dec-2019) add 50% of the flask volume with *Buffer*. Shake mechanically for 30 min. Dilute with *Buffer* to volume. Pass a portion of the supernatant through a suitable membrane filter of 0.45-µm pore size.

Chromatographic system

(See [Chromatography \(621\)](#), [System Suitability](#).)

Mode: LC

Detector: UV 250 nm. ▲For *Identification B*, use a diode array detector in the range of 200–400 nm.▲ (USP 1-Dec-2019)

Column: 4.6-mm × 25-cm; 5-µm packing [L7](#)

Column temperature: 30°

Flow rate: 1 mL/min

Injection volume: 20 µL

Run time: ▲NLT▲ (USP 1-Dec-2019) 2 times the retention time of ropinirole

System suitability

Samples: *System suitability solution* and *Standard solution*

Suitability requirements

Resolution: NLT 2.0 between ropinirole and ropinirole related compound B, *System suitability solution*

Relative standard deviation: NMT 2.0%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of ropinirole ($C_{16}H_{24}N_2O$) in the portion of Tablets taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times (M_{r1}/M_{r2}) \times 100$$

r_U = peak response of the *Sample solution*

r_s = peak response of the *Standard solution*

C_s = concentration of [USP Ropinirole Hydrochloride RS](#) in the *Standard solution* (mg/mL)

C_u = nominal concentration of ropinirole in the *Sample solution* (mg/mL)

M_{r1} = molecular weight of ropinirole, 260.37

M_{r2} = molecular weight of ropinirole hydrochloride, 296.84

Acceptance criteria: 90.0%–110.0% of ropinirole free base

PERFORMANCE TESTS

Change to read:

- [DISSOLUTION \(711\)](#).

Test 1

Medium: 2.9 g/L of [sodium citrate dihydrate](#) and 3.3 g/L of [anhydrous citric acid](#) in [water](#), pH 4.0; 500 mL

Apparatus 1: 50 rpm

Time: 15 min

Mobile phase: [Acetonitrile](#) and *Medium* (1:4)

Standard solution: ▲0.0045 mg/mL▲ (USP 1-Dec-2019) of [USP Ropinirole Hydrochloride RS](#) in *Medium*

Sample solution: Pass a portion of the solution through a suitable filter of 0.45-μm pore size, discarding the first few milliliters. Dilute with *Medium* to a concentration similar to the *Standard solution*.

Chromatographic system

(See [Chromatography \(621\)](#), *System Suitability*.)

Mode: LC

Detector: UV 250 nm

Column: 3.0-mm × 7-cm; 5-μm packing [L1](#)

Flow rate: 0.6 mL/min

Injection volume: 50 μL

Run time: ▲NLT▲ (USP 1-Dec-2019) 3 times the retention time of ropinirole

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 2.0

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of ropinirole ($C_{16}H_{24}N_2O$) dissolved:

$$\text{Result} = (r_u/r_s) \times (C_s/L) \times D \times (M_{r1}/M_{r2}) \times V \times 100$$

r_u = peak response from the *Sample solution*

r_s = peak response from the *Standard solution*

C_s = concentration of [USP Ropinirole Hydrochloride RS](#) in the *Standard solution* (mg/mL)

L = label claim (mg/Tablet)

D = dilution factor for the *Sample solution*

M_{r1} = molecular weight of ropinirole, 260.37

M_{r2} = molecular weight of ropinirole hydrochloride, 296.84

V = volume of *Medium*, 500 mL

Tolerances: NLT 85% (Q) of the labeled amount of ropinirole is dissolved.

Test 2: If the product complies with this test, the labeling indicates that it meets USP *Dissolution Test 2*.



Documents

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